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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,958	HUGHES ET AL.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: "Figure 6" in page 10, line 29. Applicants have submitted the original specification with one sheet of drawing containing only Figure 1. It is not clear what "Figure 6" is referring to. There is no "Figure 6" in the specification. Applicants are requested to clarify. If it is typographical error, applicants are advised to change it to "Figure 1".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of the specific psychiatric disorder such as anxiety disorder, depression and panic attacks with the specific synergistic combination of NK1 receptor antagonist and GABA analog such as [2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] and gabapentin or pregabalin, does not reasonably provide enablement for (i) the claimed prophylactic method of preventing a psychiatric disorder (required in claims 1-9); (ii) the full scope of claimed method in treating psychiatric disorders (required in claims 1-8); and (iii) the full scope of claimed NK1 receptor antagonist and a GABA analog synergistic combinations (required in claims 1-6 and 9). The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: 1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

With respect to the prophylaxis against psychiatric disorder,

Nature of the Invention: All rejected claims are drawn to the methods of preventing a psychiatric disorder in subjects with the administration of the instant composition comprising combination of a NK1 receptor antagonist and a GABA analog. The nature of the invention is extremely complex in that it encompasses anticipating multiple complex disorders having unrelated manifestations and subsequently administering the instant composition.

State of the Art: The state of the art does not recognize the administration of compositions to prevent or cure the disorders as required in the instant claims. The state of the art recognizes the treatment of the symptoms of these disorders but not their cure. For instance, there is no known cure for schizophrenia, anxiety disorders, bipolar disorder or post-traumatic stress disorder (PTSD).

Relative Skill of Those in the Art: The relative skill of those in the pharmaceutical art is high.

Predictability of the Art: The lack of significant guidance from the specification or the prior art with regard to completely eliminating or preventing psychiatric disorders in mammals with the administration of the instant composition makes practicing the claimed invention unpredictable in terms of the prevention of the disease.

Breadth of Claims: The complex nature of the claims is exacerbated by the breadth of the claims. The breadth of claims encompasses prevention of multitude of extremely complex disorders characterized by anxiety, mood swings, depression, loss of contact with reality or other behavioral or psychological problems including personality disorders, drug dependence (e.g., alcoholism, opioid dependency, cocaine dependency, etc...), physchosexual disorders, neuroses (e.g., anxiety disorders, phobia, obsessive-compulsive disorder, etc...), mood disorders, schizophrenic disorders, paranoid disorders and suicidal behavior.

Guidance of the Specification: The guidance given by the specification on how to prevent the disorders is absent. Guidance for treatment of anxiety disorder is provided (Figure 1 and Examples), however, no evidence that the claimed conditions are prevented is provided.

The Presence or Absence of Working Examples: As stated above, the instant specification discloses only the treatment of anxiety disorder with [2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester (CI-1021) alone or in combination with gabapentin or pregabalin.

The Amount of Experimentation Necessary: The art demonstrates treatment of the specific psychiatric disorder such as anxiety disorder, panic attacks, social phobia and depression in mammals, but does not teach elimination (prevention) of these conditions. Therefore, the practitioner would turn to trial and error experimentation to use the instant compositions for

preventing the claimed psychiatric disorders in mammals, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

For examination purposes, the phrase "preventing" is interpreted as "treating" the instant conditions.

With respect to the full scope of the claimed treatment of psychiatric disorders,

Nature of the Invention: The claims are drawn to the method of treating a psychiatric disorder in subjects with the administration of the instant composition comprising combination of a NK1 receptor antagonist and a GABA analog. The nature of the invention is extremely complex in that it encompasses anticipating multiple complex disorders having unrelated manifestations and subsequently administering the instant composition.

State of the Art: The state of the art does not recognize the administration of compositions to treat full scope of the disorders as required in the instant claims. The state of the art recognizes the treatment of the specific psychiatric disorders or symptoms of the specific psychiatric disorders.

Relative Skill of Those in the Art: The relative skill of those in the pharmaceutical art is high.

Predictability of the Art: The unpredictability of the pharmaceutical art is very high.

Breadth of Claims: The breadth of the claims is very broad. The breadth of claims encompasses multitude of extremely complex disorders characterized by anxiety, mood swings, depression, loss of contact with reality or other behavioral or psychological problems including

personality disorders, drug dependence (e.g., alcoholism, opioid dependency, cocaine dependency, etc...), physchosexual disorders, neuroses (e.g., anxiety disorders, phobia, obsessive-compulsive disorder, etc...), mood disorders, schizophrenic disorders, paranoid disorders and suicidal behavior that may have unrelated underlying pharmacological mechanism or etiology.

Guidance of the Specification: The guidance given by the specification on how to treat full scope of the claimed psychiatric disorders is insufficient. Guidance for treatment of anxiety disorder is provided (Figure 1 and Examples), however, the specification does not provide adequate representation for the treatment of full scope of the claimed conditions.

The Presence or Absence of Working Examples: As stated above, the instant specification discloses only the treatment of anxiety disorder with [2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester (CI-1021) alone or in combination with gabapentin or pregabalin.

The Amount of Experimentation Necessary: The art demonstrates treatment of the specific psychiatric disorder, for example anxiety disorder, panic attacks and depression in mammals, but does not teach the treatment of all of the conditions required by instant invention. Therefore, the practitioner would turn to trial and error experimentation to use the instant compositions for the treatment of all psychiatric disorders (e.g., alcoholism, opioid dependency, cocaine dependency, physchosexual disorders, obsessive-compulsive disorder, bipolar disorder, mood disorders, schizophrenic disorders, paranoid disorders, suicidal behavior, etc...) in mammals, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

With respect to the full scope of claimed genus NK1 receptor antagonist and a GABA analog synergistic combinations,

Nature of the Invention: The claims are drawn to the methods of treating a psychiatric disorder in subjects with the administration of the instant composition comprising synergistic combination of a NK1 receptor antagonist and a GABA analog. The nature of the invention is extremely complex in that it encompasses anticipating multiple complex disorders having unrelated manifestations and subsequently administering the instant composition.

State of the Art: The compounds of the invention are NK1 receptor antagonist and GABA analog.

Relative Skill of Those in the Art: The relative skill of those in the pharmaceutical art is high.

Predictability of the Art: The unpredictability of the pharmaceutical art is very high.

Breadth of Claims: The breadth of the instant claims is very broad due to the vast number of possible compounds of that are described as being NK1 receptor antagonist or GABA analog. Furthermore, the breadth of the instant claim is exacerbated by multitude of possible combination of NK1 receptor antagonist and GABA analogue having synergistic effect.

Guidance of the Specification: The specification provides no guidance, in the way of enablement for the full scope of NK1 receptor antagonist and GABA analogue other than disclosed 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester (CI-1021) and gabapentin or pregabalin combination (Examples). The specification fails to provide sufficient information or guidance that all compounds that are

potentially suitable for the invention which have been incorporated by references will work similarly as to 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester (CI-1021) or gabapentin and pregabalin. Numerous possible compounds that are incorporated by references are not necessarily structurally related to each other, and the skill artisan would have not known that which compounds of the claimed NK1 receptor antagonist and GABA analogue in combination are capable of accomplishing the desired result of the claimed invention without undue amount of experimentation. Furthermore, the specification provides inadequate representation or guidance that the disclosed combination of drugs, namely 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester (CI-1021) or gabapentin and pregabalin, would be a reference to other possible synergistic combinations of drugs.

The Presence or Absence of Working Examples: As stated above, the instant specification discloses only the treatment of anxiety disorder with [2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester (CI-1021) alone or in combination with gabapentin or pregabalin.

The Amount of Experimentation Necessary: The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in the determining whether "undue experimentation" is required to make and use the instant invention. For these reasons, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine all of NK1 receptor antagonist and a GABA analog combination that would be enabled in this specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10- 11 provide for the use of a composition comprising synergistic amounts of a NK1 receptor antagonist and a GABA analog, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

4. Claims 10-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

For examination purposes, the claims 10-11 are interpreted as " a method for the treatment of a psychiatric disorder".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horwell et al. (US 5,594,022) in view of Woodruff (US 5,792,796).

Horwell teaches the use of the claimed 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] (herein known as carbamic acid, 1-(1H-indol-3-ylmethyl)-1-methyl-2-oxo-2-[(1-phenylethyl)amino]ethyl] -, 2-benzofuranylmethylester [R-(R*,S*)]) as a NK-1 receptor antagonist for the treatment of psychiatric disorders such as anxiety, panic, depression, schizophrenia and addiction disorders (column 2, lines 3-7; column 8, lines 4-6; Example 63; column 12, lines 27-30; claim 22).

Woodruff teaches the use of gabapentin as a GABA analog for the treatment of psychiatric disorders such as anxiety and panic (abstract; column 3, lines 10-11; column 3, lines 56-59).

The teaching of Horwell differs from the claimed invention in (i) the combination use of NK1 receptor antagonist and GABA analog, namely 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] and gabapentin combination, for the treatment of psychiatric disorder such as anxiety and panic attack; and (ii) the specific dosage amount of GABA analog and NK1 receptor antagonist in ratio of "from 50:1 to 1:1 expressed as parts by weight" and "20:1 expressed as parts by weight" in claims 2 and 3 respectively. To incorporate such teaching into the teaching of Horwell, would have been obvious in view of Woodruff who teaches the use of gabapentin as GABA analog for the treatment of anxiety and panic attack.

The above references in combination make clear that NK1 receptor antagonist such as 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] and GABA analog such as gabapentin have been individually used for the treatment of psychiatric disorder such as anxiety and panic attack. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

With respect to the claimed synergistic effect associated with the combined use of NK1 receptor antagonist (i.e., 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-

carbamic acid benzofuran-2-ylmethyl ester) and GABA analogue (i.e., gabapentin) in treating psychiatric disorders, there seems to be no clear evidence in the instant specification to support the existence of any such synergistic effect. In particular, the method of present Example 1 or Figure 1 only appears to have been carried out using the Applicants' preferred NK1 receptor antagonist, i.e., 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester (CI-1021). There seem to be no experimental results relating to the combined use of the claimed NK1 receptor antagonist with the GABA analogue for the treatment of psychiatric disorder. Hence, in the absence of any proven surprising or unexpected results associated with the use of the NK1 receptor antagonist in combination with the GABA analogue to treat the claimed condition, it is considered that the present claims merely define obvious combined treatments, the additive effect of each active component. Therefore, the above references in combination make obvious the claimed invention.

With respect to the specific dosage ratio of the GABA analog relative to the NK1 receptor antagonist required in claims 2 and 3, the determination of the specific dosage amounts in the claimed ratio having optimum therapeutic index is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum ratio to get the maximum effect of the drug combination. Those of ordinary skill in the art would have been readily optimized effective dosage amounts in the ratio as determined by good medical practice and the clinical condition of the individual patient. Especially in light of dosage information taught in the prior art, those of ordinary skill in the art would have been arrived at the claimed invention without undue amount of experimentation.

6. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horwell et al. (US 5,594,022) in view of Silverman et al. (US 5,563,175).

Horwell teaches the use of the claimed 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] (herein known as carbamic acid, 1-(1H-indol-3-ylmethyl)-1-methyl-2-oxo-2-[(1-phenylethyl)amino]ethyl] -, 2-benzofuranylmethylester [R-(R*,S*)]) as a NK-1 receptor antagonist for the treatment of psychiatric disorders such as anxiety, panic, depression, schizophrenia and addiction disorders (column 2, lines 3-7; column 8, lines 4-6; Example 63; column 12, lines 27-30; claim 22).

Silvermann teaches the use of GABA analogue such as pregabalin ((S)-(+)-4-amino-3-(2-methylpropyl)butanoic acid or 3-isobutyl GABA) for the treatment of psychiatric disorders such as anxiety, depression and psychosis (column 1, lines 19-21; column 3, lines 53-65).

The teaching of Horwell differs from the claimed invention in the combination use of NK1 receptor antagonist and GABA analog, namely 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] and pregabalin, for the treatment of psychiatric disorder such as anxiety and depression. To incorporate such teaching into the teaching of Horwell, would have been obvious in view of Silverman who teaches the use of GABA analog such as pregabalin for the treatment of anxiety, depression and psychosis.

The above references in combination make clear that NK1 receptor antagonist such as 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] and GABA analog such as pregabalin have been individually used for the treatment of psychiatric disorder such as anxiety and depression. It is obvious to combine two

compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

With respect to the claimed synergistic effect associated with the combined use of NK1 receptor antagonist (i.e., 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester) and GABA analogue (i.e., pregabalin) in treating psychiatric disorders, there seems to be no clear evidence in the instant specification to support the existence of any such synergistic effect. In particular, the method of present Example 1 or Figure 1 only appears to have been carried out using the Applicants' preferred NK1 receptor antagonist, i.e., 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester (CI-1021). There seem to be no experimental results relating to the combined use of the claimed NK1 receptor antagonist with the GABA analogue for the treatment of psychiatric disorder. Hence, in the absence of any proven surprising or unexpected results associated with the use of the NK1 receptor antagonist in combination with the GABA analogue to treat the claimed condition, it is considered that the present claims merely define obvious combined treatments, the additive effect of each active component. Therefore, the above references in combination make obvious the claimed invention.

Conclusion

7. No Claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon